IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

SHIRLEY E. SHEFFER, *et al.*,

Plaintiffs,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.

:

:

:

Case No. 3:12-cv-238

JUDGE WALTER H. RICE

DECISION AND ENTRY SUSTAINING IN PART AND OVERRULING IN PART DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION'S *DAUBERT* MOTION TO EXCLUDE CAUSATION TESTIMONY OF PLAINTIFFS' EXPERT WITNESSES (DOC. #32); SUSTAINING IN PART AND OVERRULING IN PART DEFENDANT'S MOTION FOR SUMMARY JUDGMENT (DOC. #30)

Shirley E. Sheffer (hereafter "Sheffer"), and her husband, Scott Sheffer, filed suit against Novartis Pharmaceuticals Corporation ("NPC"). They allege that Sheffer developed osteonecrosis of the jaw ("ONJ") as a result of using NPC's nitrogenous bisphosphonate drug, Zometa®. Their Second Amended Complaint asserts several claims under the Ohio Products Liability Act, Ohio Revised Code §§ 2307.71-2307.80, and a claim for loss of consortium. This matter is currently before the Court on two pending motions: (1) Defendant NPC's *Daubert* Motion to Exclude Causation Testimony of Plaintiffs' Expert Witnesses (Doc. #32); and (2) Defendant NPC's Motion for Summary Judgment (Doc. #30).

I. Background and Procedural History

In May of 2005, Shirley Sheffer was diagnosed with Stage IV breast cancer that had metastasized to her bones. Her oncologist, Dr. John Haluschak, prescribed Zometa®, an intravenous nitrogenous bisphosphonate drug produced and marketed by NPC. Zometa® is approved by the Food and Drug Administration ("FDA"), and has proven very effective in preventing bone pain, fractures and other skeletal complications in patients with cancer that has metastasized to the bone.

Sheffer alleges that, as a result of taking Zometa®, she developed osteonecrosis of the jaw ("ONJ"), a painful, debilitating, and disfiguring condition involving the death of part of the jawbone. In March of 2006, she began experiencing problems with tooth #18. Her dentist, Dr. Bryan Harju, noted exposed bone near that tooth and referred her to Dr. Paul Kroger, a periodontist. Dr. Kroger, in turn, referred her to an oral surgeon, Dr. Victor Kim.

Dr. Kim knew that patients like Sheffer, who were taking bisphosphonates, had an increased risk of developing ONJ and should avoid invasive dental procedures. Nevertheless, he decided that tooth #18 could not be salvaged and had to be extracted. A biopsy ruled out metastases, and revealed necrotic tissue compatible with ONJ. Because they suspected that her ONJ was related to her use of Zometa®, Dr. Kim and Dr. Haluschak decided to discontinue the drug. The site of the extraction later became infected.

In October of 2006, tooth #19 also became infected. Because of Sheffer's prior use of Zometa®, Dr. Kim recommended that she have a root canal, but she

chose to have the tooth extracted instead. Thereafter, she suffered intermittent bouts of infection and severe pain. She sought medical care from Dr. Sorg, an infectious disease doctor. In October of 2008, Sheffer suffered a broken jaw near where tooth #18 had been extracted.

On May 28, 2008, Sheffer and her husband, residents of Yorkshire, Ohio, filed suit against NPC in the United States District Court for the District of Columbia. They originally asserted common law claims of strict product liability, negligent manufacture, negligent failure to warn, breach of express warranty, breach of implied warranty, and loss of consortium.

Their case was one of hundreds of similar cases filed across the country, all alleging that NPC knew or should have known that Zometa® and its predecessor drug, Aredia®, cause ONJ, and that NPC failed to provide timely and adequate notice to the public and to health care professionals. The Judicial Panel on Multi-District Litigation consolidated the cases for pretrial purposes, and the cases were divided into several litigation "waves." *In re Aredia® and Zometa® Products Liability Litigation*, No. 3:06-MD-1760 (M.D. Tenn.).

In January of 2012, Sheffer's case was remanded to the United States District Court for the District of Columbia, and in July of 2012, was transferred to the United States District Court for the Southern District of Ohio. On November 13, 2012, NPC filed a Motion for Summary Judgment. Doc. #30. In connection with that motion, NPC also filed a *Daubert* Motion to Exclude Causation Testimony of Plaintiffs' Expert Witnesses. Doc. #32.

In reviewing the pending motions, the Court noted that the parties agreed that Plaintiffs' claims were subject to the Ohio Products Liability Act ("OPLA"). Because the OPLA abrogates "all common law product liability claims or causes of action," Ohio Revised Code § 2307.71(B), the Court ordered Plaintiffs to file an Amended Complaint, reasserting their claims under the OPLA. Doc. #54.

On July 29, 2013, Plaintiffs filed a Second Amended Complaint, Doc. #55, asserting five causes of action: (1) strict liability design defect, under Ohio Revised Code § 2307.75; (2) negligence, inadequate warning, under Ohio Revised Code § 2307.76(A); (3) nonconformance with manufacturers' representation, under Ohio Revised Code § 2307.77; (4) loss of consortium; and (5) punitive and exemplary damages, under Ohio Revised Code § 2307.80.[1]

Before addressing the merits of these claims, the Court turns first to NPC's *Daubert* Motion to Exclude Causation Testimony of Plaintiffs' Expert Witnesses. Doc. #32.

II. *Daubert* Motion to Exclude Causation Testimony of Plaintiffs' Expert Witnesses (Doc. #32)

Citing Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), Defendant NPC has moved to exclude the testimony of Plaintiffs' expert witnesses concerning the issue of specific

---

[1] It is not clear why Plaintiffs labeled this a "Second Amended Complaint." No First Amended Complaint appears on the docket. Nonetheless, the Court will refer to this filing, as Plaintiffs did, as their Second Amended Complaint.

causation, *i.e.*, whether Sheffer's use of Zometa® caused her to develop ONJ. Doc. #32. NPC seeks to exclude specific causation testimony of Sheffer's treating physicians, Dr. John Haluschak, Dr. Victor Kim, Dr. Bryan Harju, and Dr. Timothy Sorg. NPC also seeks to exclude the testimony of Plaintiffs' retained expert witness, Dr. Talib Najjar.

Federal Rule of Evidence 702 governs the admissibility of expert witness testimony. It states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

In *Daubert*, the Supreme Court assigned the trial judge a "gatekeeping" function. The trial judge must ensure that the expert witness's testimony "both rests on a reliable foundation and is relevant to the task at hand." 509 U.S. at 589. The court need not hold a hearing, but "is required to make an initial assessment of the relevance and reliability of the expert testimony." *Greenwell v. Boatwright*, 184 F.3d 492, 498 (6th Cir. 1999).

There is no need for a hearing in this case, because there is sufficient evidence in the record to allow the Court to determine whether the proposed expert witness testimony is relevant and reliable. For the reasons set forth below, the Court SUSTAINS NPC's motion to exclude specific causation testimony by Sheffer's treating physicians, but OVERRULES NPC's motion to exclude specific causation testimony of Dr. Najjar.

A. Treating Physicians

As the Sixth Circuit noted in *Gass v. Marriott Hotel Services, Inc.*, 558 F.3d 419 (6th Cir. 2009):

> Generally, a treating physician may provide expert testimony regarding a patient's illness, the appropriate diagnosis for that illness, and the cause of the illness. *See Fielden v. CSX Transp., Inc.*, 482 F.3d 866, 870 (6th Cir. 2007). However, a treating physician's testimony remains subject to the requirement set forth in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), that an expert's opinion testimony must "have a reliable basis in the knowledge and experience of his discipline." *Id.* at 592, 113 S.Ct. 2786.

Gass, 558 F.3d at 426.

There is a distinction between diagnosing a medical condition and determining its cause. Typically, specific causation is determined through the use of a differential etiology, whereby all possible causes are considered and then ruled out one by one until the "most likely cause" is identified. Relevant questions include:

> (1) Did the expert make an accurate diagnosis of the nature of the disease? (2) Did the expert reliably rule in the possible causes of it? (3) Did the expert reliably rule out the rejected

> causes? If the court answers "no" to any of these questions, the court must exclude the ultimate conclusion reached.

Tamraz v. Lincoln Elec. Co., 620 F.3d 665, 673-74 (6th Cir. 2010).

NPC argues that specific causation testimony of Sheffer's treating physicians must be excluded because none is an expert in diagnosing ONJ and none has expressed a definitive opinion, based on reliable methodology, about the cause of Sheffer's ONJ. The Court agrees.

Dr. Haluschak, Sheffer's treating oncologist, admitted at his deposition that he does not treat ONJ, and is not an expert in determining the cause of ONJ. Haluschak Dep. at 66-67 (Ex. 3 to Doc. #32). He testified that Sheffer has ONJ which "may, indeed, be related to Zometa®." He admittedly does not know for sure that her ONJ was caused by the Zometa®, but "it would be logical to say that." *Id.* at 214. At one point, Dr. Haluschak suspected that her use of the cancer drug Avastin® might be a contributing factor,[2] but there is no evidence that he conducted a differential etiology to rule out any other causes of her jaw problems.

Dr. Harju, Sheffer's general dentist, does not consider himself an expert on ONJ or its risk factors. Harju Dep. at 47 (Ex. 4 to Doc. #32). After observing exposed bone in her mouth in March of 2006, he speculated that she had

---

[2] Dr. Haluschak noted that Sheffer's jaw pain diminished in 2007 when he discontinued Avastin®, and reappeared when she resumed its use. Exs. 15 and 16 to Doc. #32. He contacted Avastin's® manufacturer to inquire about a possible connection but, as he recalls, the manufacturer did not know of any published studies linking Avastin® to ONJ. Haluschak Dep. at 148-150, 157.

"possibly drug-induced osteonecrosis because she has been treated with Zometa®." *Id.* at 73. He conceded, however, that he conducted no tests, and "actually did not make a diagnosis." *Id.* at 76.

Likewise, Dr. Sorg, Sheffer's infectious disease specialist, does not claim to be an expert on Zometa®, or on determining the cause of ONJ. 7/27/11 Sorg Dep. at 20 (Ex. 18 to Doc. #32). When asked whether he diagnosed Sheffer with ONJ, he testified that he was "pretty certain" that he "relied on other people to diagnose the nature of the necrosis in the jaw and what caused it." *Id.* at 18-19.

Sheffer apparently concedes that Dr. Haluschak, Dr. Harju, and Dr. Sorg are not qualified to offer opinions on specific causation. Citing the MDL court, she argues, however, that they should be permitted to testify about her "symptoms, tests, diagnosis and treatment, as to what they did in response to her condition and as to what they would have done differently, if anything, had they known of any additional warnings." *In re: Aredia and Zometa Products Liability Litigation (Deutsch)*, No. 3:06-md-1760, 2009 WL 2496886, at *3 (M.D. Tenn. Aug. 13, 2009).

NPC concedes that Dr. Haluschak, Dr. Harju, and Dr. Sorg may testify about their treatment of Sheffer, but argues that they are not qualified to opine about the cause of her ONJ. The Court agrees. Not only do they disavow any expertise in this area, but none has expressed a definitive opinion on the actual cause of Sheffer's jaw problems. Therefore, they will not be permitted to testify about whether Sheffer's use of Zometa® caused her ONJ.

Dr. Kim is Sheffer's oral and maxillofacial surgeon. He diagnosed her with ONJ and has treated her for that disease since March of 2006. He admits, however, that he is not an expert in determining the *cause* of ONJ. Kim Dep. at 36 (Ex. 10 to Doc. #32). In March of 2006, he diagnosed Sheffer with an infection in her jaw. Although he had "some ideas" about the source of that infection, he does not know for sure what caused it. *Id.* at 56. The pathology report ruled out metastatic disease. Kim Dep. at 67 (Ex. J. to Doc. #44).

NPC notes, however, that Dr. Kim ruled out no other possible alternative causes of Sheffer's ONJ. The Court finds that Dr. Kim's differential etiology does not satisfy the reliability standards required by *Daubert*. Accordingly, he will not be permitted to offer an expert opinion on specific causation. He will, however, be permitted to testify about his diagnosis and treatment of Sheffer's ONJ.

B. Retained Expert Dr. Talib Najjar

Dr. Talib Najjar is a board-certified oral pathologist and oral maxillofacial surgeon, retained by Plaintiffs as an expert witness on the question of specific causation. Dr. Najjar is a specialist in diseases of the jaw, has researched ONJ in rats, and has treated several patients with bisphosphonate-induced ONJ. In his report, he concludes, to a reasonable degree of medical certainty, that Sheffer developed ONJ as a result of her treatment with Zometa®. Ex. 20 to Doc. #32. NPC asks the Court to exclude his specific causation testimony.

Citing *Foster v. Legal Sea Foods, Inc.*, No. CCB-03-2512, 2008 WL 2945561, at *10 (D. Md. July 25, 2008), and *Grimes v. Hoffman-LaRoche, Inc.*,

907 F. Supp. 33, 38 (D.N.H. 1995), NPC argues that establishing general causation, *i.e.*, that bisphosphonate drugs cause ONJ, is a prerequisite to establishing specific causation, *i.e.*, that bisphosphonate drugs caused ONJ in Sheffer's case. NPC maintains that because Dr. Najjar has admitted that the causal relationship between the occurrence of ONJ and Zometa® has not yet been scientifically proven through controlled studies, he should not be permitted to testify that this drug caused ONJ in Sheffer's case. 3/17/09 Najjar Dep. at 184, 284, 330 (Ex. 21 to Doc. #32).

Nevertheless, the fact that the causal link between the drugs and ONJ has not yet been conclusively established *through controlled studies* does not mean that Plaintiffs cannot establish general causation. Dr. Najjar testified that, despite the lack of controlled studies, there is a "strong association" between bisphosphonate drugs and ONJ. 3/17/09 Najjar Dep. at 284. Moreover, the MDL Court has already determined that genuine issues of material fact exist concerning general causation. *In re: Aredia and Zometa Prods. Liability Litigation*, No. 3:06-md-1760, Docs. ##2763, 2764 (M.D. Tenn. Aug. 9, 2009). Under these circumstances, the absence of controlled studies conclusively establishing general causation does not provide any basis for excluding Dr. Najjar's specific causation opinion.

NPC also argues that Dr. Najjar's opinion should be excluded because he spent only five or six hours reviewing Sheffer's medical records and failed to review the deposition testimony of her treating physicians. 9/14/11 Najjar Dep. at

21, 69 (Ex. 8 to Doc. #32). Any challenges to the sufficiency of his review of Sheffer's medical records, however, go to the weight of his testimony, not its admissibility.

NPC further argues that Dr. Najjar's opinion is based on unreliable methodology. NPC notes that Dr. Najjar admitted that there is some evidence that Avastin® may cause ONJ. *Id.* at 92-93. He also admitted that the lytic lesions found in Sheffer's jaw could be evidence of metastasis, and metastasis can lead to necrosis. *Id.* at 106; 3/17/09 Najjar Dep. at 114. In addition, he admitted that osteomyelitis can lead to necrosis. 3/17/09 Najjar Dep. at 84.

NPC argues that Dr. Najjar's differential etiology is flawed in that he admitted that he could not rule out Sheffer's use of Avastin® as a possible cause of her ONJ. 9/14/11 Najjar Dep. at 97. He also testified that he could not rule out the possibility that Sheffer had metastasis to her jaw, or had osteomyelitis. *Id.* at 107, 110.

As Sheffer points out, however, Dr. Najjar did specifically rule out numerous possible alternative causes, including some of those cited by NPC. His report states:

> Mrs. Sheffer's [ONJ] could, radiographically mimic other bony lesions including *metastatic breast cancer*, fibrosseous lesions, florid osseous dysplasia, osteoporosis, *osteomyelitis*, prolonged corticosteroid and phosphorous exposure. However, it is my opinion and based on Mrs. Sheffer's records that the above conditions are ruled out in her case. Other dental, periodontal conditions, chemotherapy, anemia, malnutrition, a trauma may in some cases make [ONJ] symptoms more severe. They did not cause it however. It is difficult to access [sic] the individual influence of such conditions in Mrs. Sheffer's case.

Ex. 20 to Doc. #32 (emphasis added).

Moreover, Dr. Najjar's failure to conclusively rule out every possible alternative cause does not necessarily render his testimony deficient under *Daubert*. *See Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001) ("A medical expert's opinion based upon differential diagnosis normally should not be excluded because the expert has failed to rule out every possible alternative cause of a plaintiff's illness . . . In such cases, the alternative causes suggested by a defendant normally affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony.").

Based on the evidence presented, the Court finds that Dr. Najjar is qualified to offer an opinion regarding specific causation, and that his opinion is based on reliable methodology, *i.e.*, a differential etiology. NPC, of course, is free to cross-examine him concerning the basis of his opinion. The Court therefore overrules Defendant's motion to exclude Dr. Najjar's testimony on the issue of specific causation.

III. Motion for Summary Judgment

A. Standard of Review

Summary judgment must be entered "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp.*

v. Catrett, 477 U.S. 317, 322 (1986). The moving party always bears the initial responsibility of informing the court of the basis for its motion, and identifying those portions of the record which it believes demonstrate the absence of a genuine issue of material fact. *Id.* at 323; *see also Boretti v. Wiscomb*, 930 F.2d 1150, 1156 (6th Cir. 1991).

"Once the moving party has met its initial burden, the nonmoving party must present evidence that creates a genuine issue of material fact making it necessary to resolve the difference at trial." *Talley v. Bravo Pitino Rest., Ltd.*, 61 F.3d 1241, 1245 (6th Cir. 1995); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). Once the burden of production has so shifted, the party opposing summary judgment cannot rest on its pleadings or merely reassert its previous allegations. It is not sufficient to "simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Rule 56 "requires the nonmoving party to go beyond the [unverified] pleadings" and present some type of evidentiary material in support of its position. *Celotex*, 477 U.S. at 324. "The plaintiff must present more than a scintilla of evidence in support of his position; the evidence must be such that a jury could reasonably find for the plaintiff." *Michigan Prot. & Advocacy Serv., Inc. v. Babin*, 18 F.3d 337, 341 (6th Cir. 1994).

Summary judgment shall be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "Summary judgment will not lie if the dispute

about a material fact is 'genuine,' that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson*, 477 U.S. at 248. In determining whether a genuine dispute of material fact exists, a court must assume as true the evidence of the nonmoving party and draw all reasonable inferences in favor of that party. *Id.* at 255. If the parties present conflicting evidence, a court may not decide which evidence to believe. Credibility determinations must be left to the fact-finder. 10A Wright, Miller & Kane, *Federal Practice and Procedure* Civil 3d § 2726 (1998).

In determining whether a genuine dispute of material fact exists, a court need only consider the materials cited by the parties. Fed. R. Civ. P. 56(c)(3). "A district court is not . . . obligated to wade through and search the entire record for some specific facts that might support the nonmoving party's claim." *InterRoyal Corp. v. Sponseller*, 889 F.2d 108, 111 (6th Cir. 1989), *cert. denied*, 494 U.S. 1091 (1990). If it so chooses, however, the court may also consider other materials in the record. Fed. R. Civ. P. 56(c)(3).

B. Analysis

Plaintiffs' Second Amended Complaint asserts three claims under the OPLA: (1) a design defect claim under Ohio Revised Code § 2307.75; (2) an inadequate warning claim under Ohio Revised Code § 2307.76(A); and (3) a nonconformance with manufacturers' representation claim under Ohio Revised Code § 2307.77. Plaintiffs also seek punitive and exemplary damages under Ohio Revised Code

§ 2307.80. In addition, Scott Sheffer asserts a common law claim of loss of consortium. NPC has moved for summary judgment, arguing that these claims are time-barred and that they fail on the merits.[3]

1. Statute of Limitations

Ohio Revised Code § 2305.10(A) provides that all product liability claims must be brought within two years after the cause of action accrues. Although Sheffer learned in March of 2006, that her ONJ was likely caused by the Zometa®, she did not file suit until May 27, 2008, more than two years later. NPC therefore argues that her claims are time-barred.

Plaintiffs disagree. They filed suit in the United States District Court for the District of Columbia, which has a three-year statute of limitations. D.C. Code § 12-301(8). This Court, as the transferee court in a diversity action, must apply the law of the transferor court. *See Ferens v. John Deere Co.*, 494 U.S. 516, 527-28 (1990); *Klayman v. Barmak*, 602 F. Supp.2d 110, 115 (D.D.C. 2009).

NPC acknowledges that this is the law. It argues, however, that the District of Columbia has no possible connection to this litigation. According to NPC, it appears that Plaintiffs filed suit there only because their claims were already time-barred in Ohio. NPC maintains that such egregious forum shopping should not be allowed. According to NPC, because Ohio has a "more significant relationship" to the case, the Ohio statute of limitations should govern.

---

[3] The Court gave NPC the opportunity to modify its Motion for Summary Judgment after the Second Amended Complaint was filed, Doc. #54, but NPC decided that no modifications were needed, Doc. #57.

Plaintiffs note, however, that this issue has already been decided. In its order granting NPC's motion to transfer this case from the United States District Court for the District of Columbia to the Southern District of Ohio, the court specifically held that "the District of Columbia's statute of limitations applies to this lawsuit" because, under the District of Columbia's choice-of-law rules, the statute of limitations is considered procedural. *Sheffer v. Novartis Pharm. Corp.*, 873 F. Supp.2d 371, 379-80 (D.D.C. 2012). Since this is the law of the case, it would be improper to revisit the issue. Accordingly, the Court concludes that Plaintiffs' claims are not barred by the statute of limitations.

2. Count I: Strict Liability, Product Defective in Design or Formulation (Ohio Revised Code § 2307.75)

The OPLA provides that "a product is defective in design or formulation if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation . . . exceeded the benefits associated with that design or formulation . . . " Ohio Revised Code § 2307.75(A). But a prescription drug "is not defective in design or formulation because some aspect of it is unavoidably unsafe, if the manufacturer . . . provides adequate warning . . ." Ohio Revised Code § 2307.75(D). The statute further provides that:

> A product is not defective in design or formulation if, at the time the product left the control of its manufacturer, a practical and technically feasible alternative design or formulation was not available that would have prevented the harm for which the claimant seeks to recover compensatory damages without substantially impairing the usefulness or intended purpose of the product.

Ohio Revised Code § 2307.75(F).

In Count I of the Second Amended Complaint, Plaintiffs allege that Zometa® is unreasonably dangerous for normal use due to its defective design and inadequate warnings. Plaintiffs maintain that smaller doses of Zometa® were equally effective and carried far less risk of ONJ. They also allege that Aredia®, Zometa's® predecessor drug, was safer, equally effective, and could be taken for a longer period of time with less risk. Sec. Am. Compl. ¶¶28, 30.

NPC argues that it is entitled to summary judgment on this claim because Sheffer's own expert, Dr. Richard Marx, has conceded that the benefits of bisphosphonate drugs outweigh the risks. He testified that "runaway cancer is more important and life-threatening than ONJ." ONJ is painful, but manageable. Therefore, "we defer to the oncologist." 5/15/07 Marx Dep. at 167, 174 (Ex. 5 to Doc. #30). Moreover, Dr. Haluschak, Sheffer's treating oncologist, continues to prescribe Zometa® and Aredia® because they substantially "reduce the skeletal related events" and "the risks associated with not giving [the drugs] are much higher than risks associated with giving [them]." Haluschak Dep. at 107-08, 224 (Ex. 14 to Doc. #30). NPC further notes that the FDA, charged with making an independent risk-benefit calculation, continues to approve Zometa® and Aredia®.

In addition, NPC argues that: (1) because the warnings given were adequate, the drugs cannot be deemed defective in design or formulation, *see* Ohio Revised Code § 2307.75(D); and (2) Plaintiffs have not satisfied their burden of producing a feasible alternative design for Zometa® that would have prevented the harm

alleged without substantially impairing the usefulness of the drug, *see* Ohio Revised Code §2307.75(F).

Sheffer's response to NPC's arguments is woefully deficient. She summarily argues only that "because the issues of dose and duration are contested, a design defect claim survives. NPC either knew a lesser dose was efficacious or willfully avoided finding out for profit reasons." Doc. #43, at 20. Sheffer cites to absolutely no expert witness testimony or other evidence to support her allegations that a lower dosage or a shorter treatment period would reduce the risk of ONJ without substantially impairing the usefulness of Zometa®, or that Aredia® was equally effective and safer than Zometa®.

Although Sheffer may very well have expert witness testimony to that effect, the Court is not obligated to dig through the record to uncover it, particularly in a case like this where the record is so voluminous. "[J]udges need not paw over the files without assistance from the parties." *Huey v. United Parcel Serv., Inc.*, 165 F.3d 1084, 1085 (7th Cir. 1999). *See also Betkerur v. Aultman Hosp. Ass'n*, 78 F.3d 1079, 1087 (6th Cir. 1996) (noting that the trial court has no "duty to search the entire record to establish that it is bereft of a genuine issue of material fact"). Rule 56 requires the nonmoving party to present some type of evidentiary material in support of its position. *Celotex*, 477 U.S. at 324. *See also* Fed. R. Civ. P. 56(c)(1)(A) (requiring party to cite to "particular parts of materials in the record").

Because Sheffer has failed to point to any evidence from which a reasonable jury could find that the foreseeable risks associated with the design or formulation of Zometa® exceeded the benefits associated with that design or formulation, and has failed to present any evidence that a safer, but equally effective, design existed, the Court SUSTAINS NPC's motion for summary judgment on this claim.

3. Count II: Negligence – Inadequate Warning (Ohio Revised Code § 2307.76(A))

Count II of the Second Amended Complaint asserts an "inadequate warning" claim under Ohio Revised Code § 2307.76(A)(1). That statute provides that a product is defective due to inadequate warning if, when it left the manufacturer's control, both of the following applied:

> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages; [and]
>
> (b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

Ohio Rev. Code § 2307.76(A)(1).

A product is defective due to inadequate *post-marketing* warning if, at a relevant time after it left the manufacturer's control, both of the following applied:

> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages; [and]

> (b) The manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

Ohio Rev. Code § 2307.76(A)(2).

To succeed on an "inadequate warning" claim, a plaintiff must prove: "(1) a duty to warn against reasonably foreseeable risks; (2) breach of this duty; and (3) an injury that is proximately caused by the breach." *Miller v. ALZA Corp.*, 759 F. Supp.2d 929, 934 (S.D. Ohio 2010) (quoting *Graham v. Am. Cyanamid Co.*, 350 F.3d 496, 514 (6th Cir. 2003)).

Sheffer alleges that NPC breached its duty to provide timely and adequate warnings to health care professionals and patients about the risk that Zometa® would cause ONJ, and that this inadequate warning was a substantial cause of her injury. NPC argues that it is entitled to summary judgment on this claim because Sheffer cannot show that NPC breached a duty to warn against reasonably foreseeable risks, or that her injury was proximately caused by the breach. Based on the evidence presented, the Court finds that genuine issues of material fact preclude summary judgment on this claim.

i) Breach of Duty

NPC maintains that it fully discharged its duty to warn Sheffer's physicians of the risks associated with Zometa®. With respect to claims of inadequate warning, the OPLA provides:

> An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it.

Ohio Revised Code § 2307.76(C).

Sheffer received her first infusion of Zometa® in May of 2005. At that time, the warning label noted that ONJ had been reported in patients using the drug, and that the majority of the cases were associated with dental procedures. The label recommended dental screening prior to beginning treatment and cautioned against invasive dental procedures while on treatment. Ex. 2 to Doc. #30. In September of 2004, NPC had sent letters to doctors warning of the risk of bisphosphonate-induced ONJ. In May of 2005, NPC sent similar letters to dentists and oral surgeons. Exs. 7 and 9 to Doc. #30.

Dr. Haluschak testified that he was aware of the risk of ONJ in 2005 when he prescribed Zometa® to Sheffer. Haluschak Dep. at 112. Likewise, Dr. Harju, Dr. Kroger, and Dr. Kim all testified that, when they treated Sheffer, they were aware of association between Zometa® and ONJ. Harju Dep. at 22-23 (Ex. 42 to Doc. #30); Kroger Dep. at 52-53 (Ex. 43 to Doc. #30); Kim Dep. at 53-54 (Ex. 18 to Doc. #30).

Despite the warnings that were given, Sheffer contends that NPC failed to adequately warn of the *magnitude* of the risk. Notably, in "Wave I" of the multi-district litigation, the MDL Court determined that genuine issues of material fact

preclude summary judgment on the issue of warning adequacy. It found that there are genuine factual disputes concerning what NPC knew or should have known and when, and whether the letters sent to doctors and dentists timely and adequately conveyed information about the risk of developing ONJ. *In re Aredia and Zometa Prods. Liability Litigation*, No. 3:06-md-1760, Docs. #2766, 2767 (M.D. Tenn. Aug. 13 2009).

Because the issues concerning breach of duty in this case are similar to those in the "Wave I" cases, the Court sees no basis for disturbing the ruling of the MDL court. The Court concludes that genuine issues of material fact preclude summary judgment on the question of whether NPC breached its duty to provide adequate warnings concerning the risk of bisphosphonate-induced ONJ.

ii) Proximate Cause

NPC also argues that Sheffer has failed to produce sufficient evidence that the alleged inadequate warning proximately caused her injury. In *Seley*, the Ohio Supreme Court explained that, in the context of a "failure to warn" claim, proximate cause involves two sub-issues: "(1) whether lack of adequate warnings contributed to the plaintiff's [use] of the drug, and (2) whether [use] of the drug constitutes a proximate cause of the plaintiff's injury." 67 Ohio St.2d at 200, 423 N.E.2d at 838. NPC argues that Sheffer's claim is deficient in both respects.

NPC first argues that Sheffer cannot prove that the lack of an adequate warning contributed to her use of Zometa®. Under Ohio law, it is presumed that if an adequate warning is given, it will be read and heeded. But where no warning is

given, or where an inadequate warning is given, a rebuttable presumption arises that the failure to adequately warn was a proximate cause of the plaintiff's use of the drug. *Id.*

This presumption may be rebutted by proof that "an adequate warning would have made no difference in the physician's decision as to whether to prescribe a drug or as to whether to monitor the patient thereafter." *Id.* at 201, 423 N.E.2d at 838. Where a treating physician unequivocally testifies that an adequate warning would not have altered the course of treatment, summary judgment is warranted. However, it is not warranted if the evidence does not affirmatively establish that the physician "would not have behaved differently had he received a different warning." *Miller*, 759 F. Supp.2d at 936 (quoting *Williams v. Lederle Laboratories*, 591 F. Supp. 381, 387 (S.D. Ohio 1984)).

NPC contends that it has successfully rebutted the presumption that the alleged failure to adequately warn was a proximate cause of Sheffer's use of the drug. According to NPC, Sheffer cannot show that a different warning would have altered her course of treatment, because Dr. Haluschak testified that, if Sheffer came to him today in the same condition she was in in May of 2005, he would still recommend that she take Zometa®. Haluschak Dep. at 107, 110.

Sheffer maintains that Dr. Haluschak's testimony is not sufficient to rebut the presumption. According to Sheffer, NPC failed to adequately disclose the *magnitude* of the risk of developing ONJ, and downplayed the causal connection by including false "alternate risk factors" on the label. Sheffer argues that a

reasonable jury could find that if Dr. Haluschak had been aware of the true magnitude of the risk, he would have disclosed that risk to her, and she would have refused to take Zometa®, thereby averting her injury.

Dr. Haluschak does not remember whether he discussed the risk of ONJ with Sheffer before recommending that she take Zometa®. *Id.* at 110, 113. Nevertheless, because he was aware of the risk, he did ask her some questions about her dental history. At that time, she had no complaints of mouth or jaw pain. *Id.* at 73, 112.

According to Sheffer, Dr. Haluschak told her that Zometa® would make her bones stronger, but he never told her about any of the associated risks, including the risk that it may cause ONJ. Sheffer Dep. at 107, 111-12 (Ex. 1 to Vecchione Decl., Doc. #5479 in Case No. 3:06-md-1760 (M.D. Tenn.)). She further testified that if she had been told about the risk of developing ONJ, she would not have taken Zometa®, even if Dr. Haluschak had recommended it. *Id.* at 181-82.[4]

NPC correctly points out that Sheffer's testimony is irrelevant absent proof that a different warning would have caused Dr. Haluschak to warn her of the risk of developing ONJ. Nevertheless, based on the evidence presented, a reasonable jury could find that a warning that more accurately conveyed the magnitude of the risk would have prompted Dr. Haluschak to disclose that risk to Sheffer.

---

[4] In this respect, the case is factually distinguishable from *D'Agnese v. Novartis Pharmaceuticals Corp.*, No. CV-12-749 (D. Az. July 2, 2013), cited by NPC in its Notice of Supplemental Authority, Doc. #56. Mr. D'Agnese continued to take Aredia® even after being warned of the risk of ONJ.

Dr. Haluschak testified that he always uses his professional medical judgment to determine which risks he must discuss with a patient. Haluschak Dep. at 87. It is his general practice to "talk about all the things that are most serious about anything that can happen with these products." *Id.* at 88. He further testified that he probably tells patients more than they want to hear. *Id.* at 110. He noted that sometimes, after hearing the associated risks, patients reject a recommended course of treatment. *Id.* at 87. He admitted that, ultimately, the final decision whether to take any particular drug rests with the patient. *Id.* at 98.

In evaluating a motion for summary judgment, the Court must draw all reasonable inferences in favor of the non-moving party. *Anderson*, 477 U.S. at 255. Based on Dr. Haluschak's deposition testimony, it can be inferred that the higher the known risk of a particular side effect and the more serious it is, the more likely it is that he would have discussed it with the patient. Notably, there is no affirmative evidence that Dr. Haluschak would *not* have discussed the risks of ONJ with Sheffer had NPC issued a stronger warning.

Drawing all reasonable inferences in Sheffer's favor, the Court finds a genuine issue of material fact concerning whether an adequate warning would have altered her course of treatment. A reasonable jury could find that if NPC had issued a different warning, Dr. Haluschak would have disclosed the risk of ONJ to Sheffer, who would have refused to take Zometa®, thereby averting her injury

entirely.[5] Ultimately, a jury will have to determine whether NPC has successfully rebutted the presumption that the alleged inadequate warning was a proximate cause of Sheffer's use of the drug.

In *Payne v. Novartis Pharmaceuticals Corporation*, No. 1:12-cv-77 (E.D. Tenn. Sept. 6, 2013), submitted by NPC as supplemental authority, Ex. 1 to Doc. #59, the plaintiff submitted a similar affidavit stating that, had she known of the risk of ONJ, she would not have taken the drug at all. That court rejected her affidavit as "entirely speculative." *Id.* at 18-19 n.9. This Court is not bound by the *Payne* ruling, and respectfully disagrees concerning the speculative nature of the statement. Moreover, Sheffer testified that even though Dr. Haluschak recommended that she undergo radiation treatment, she opted not to follow his advice because of the potential for liver damage. Sheffer Dep. at 113-14. It can be inferred that, having rejected Dr. Haluschak's advice on *that* particular matter after being fully informed of the risks, she would have no qualms about doing so again.

With respect to the question of proximate cause, NPC also argues that Sheffer cannot show that a different warning would have altered the course of her dental treatment. NPC notes that Dr. Kim determined that, despite the risks

---

[5] Sheffer also argues that a reasonable jury could find that, if an adequate warning had been given, Dr. Haluschak would have recommended that she have a pretreatment dental screening, that her dentist would have discovered that she had periodontal disease, and that, as a result, Dr. Haluschak would have altered his course of treatment. In the Court's view, this argument is much more speculative, but it may provide additional support for the Court's ruling.

involved, tooth #18 had to be extracted because it was infected. Subsequently, Sheffer, acting against Dr. Kim's advice, chose to have tooth #19 extracted rather than having a root canal. Kim Dep. at 57, 80-82 (Ex. 18 to Doc. #30). NPC therefore argues that Sheffer cannot show that the lack of an adequate warning was the proximate cause of her injury.

This argument might carry more weight if, as is often the case, Sheffer's ONJ had been triggered by the invasive dental procedures. But, according to Dr. Najjar, Sheffer's ONJ occurred spontaneously. She developed ONJ before she had either tooth extracted. Although the extractions may have contributed to the progression of her ONJ, they did not trigger its onset.[6] Najjar Dep. at 111-12 (Ex. 15 to Doc. #30). Therefore, regardless of whether different warnings would have altered the course of her dental treatment with respect to the extractions, there is still a genuine issue of material fact concerning whether the lack of adequate warning contributed to her use of Zometa®, and whether her use of Zometa® constitutes a proximate cause of her injury.

NPC also argues that Sheffer cannot prove that her use of Zometa® caused her to develop ONJ, because she has no admissible expert witness testimony on this subject. This argument, however, is foreclosed by the Court's decision

---

[6] In this respect, this case is factually distinguishable from *Zimmerman v. Novartis Pharmaceuticals Corp.*, 287 F.R.D. 357, 361-62 (D. Md. 2012), and *Eberhart v. Novartis Pharmaceuticals Corp.*, 867 F. Supp.2d 1241, 1256 (N.D. Ga. 2011).

overruling NPC's motion to exclude the testimony of Dr. Najjar, Sheffer's retained expert witness, on the topic of specific causation.

For the reasons set forth above, the Court finds that genuine issues of material fact preclude summary judgment on Count II of the Second Amended Complaint. The Court therefore OVERRULES NPC's motion for summary judgment on Sheffer's "inadequate warning" claim.

4. Count III: Nonconformance with Manufacturers' Representations (Ohio Revised Code § 2307.77)

For claims of non-conformance with manufacturers' representations, the OPLA provides as follows:

> A product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer. A product may be defective because it did not conform to a representation even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation.

Ohio Revised Code § 2307.77. To recover under this section of the OPLA, a plaintiff must prove:

1) that the manufacturer made a representation as to a material fact concerning the character or quality of the manufacturer's product;
2) that the product did not conform to that representation;
3) that the plaintiff justifiably relied on that representation; and
4) that the plaintiff's reliance on the representation was the direct and proximate cause of the plaintiff's injuries.

Gawloski v. Miller Brewing Co., 96 Ohio App.3d 160, 165, 644 N.E.2d 731, 734 (Ohio Ct. App. 1994).

In the original Complaint, and again in Count III of the Second Amended Complaint, Sheffer alleges that NPC expressly warranted that Zometa® was "safe, effective, fit and proper for its intended use." Sec. Am. Compl. ¶ 48. In its Motion for Summary Judgment, NPC relies on *In re Meridia Products Liability Litigation*, 328 F. Supp.2d 791 (N.D. Ohio 2004) for the proposition that, particularly in cases involving drugs, "asserting that a product is 'safe and effective' is not sufficiently clear to create an express warranty." *Id.* at 818. Sheffer makes little attempt to rebut this argument, arguing only that a drug warranted to *strengthen* bones instead *destroyed* her jaw bone.

Because *In re Meridia Products* involved a common law claim of breach of express warranty, rather than a claim under Ohio Revised Code § 2307.77, its applicability to this case is questionable. But even if that case is dispositive with respect to the representation that Zometa® is "safe and effective," summary judgment is not warranted on this claim.

The Second Amended Complaint cites to several *other* representations allegedly made by NPC, including:

> 50. Zometa did not conform with the express material representation of Novartis that [it] would strengthen bones, in that it weakened jaw bones and caused them to die in significant numbers.
> 51. Further, Novartis represented that "side effects were mild and transient" when in fact in significant numbers, Zometa cause serious, permanent BRONJ injury.
> 52. Further, Novartis represented by denial that its bisphosphonate drugs cause BRONJ.
> 53. Novartis represented that continued dosing with Zometa after one year was effective when it had no evidence acceptable to the FDA to that effect.

Sec. Am. Compl. ¶¶ 50-53. The Second Amended Complaint further alleges that Sheffer's health care providers reasonably relied on these representations in recommending that she use Zometa®, and that these representations were a direct and proximate cause of her injuries. *Id.* at ¶¶ 54-55.

Although the Court gave NPC the opportunity to revise its Motion for Summary Judgment after the Second Amended Complaint was filed, NPC chose not to do so. NPC has wholly failed to satisfy its initial burden of establishing the absence of a genuine issue of material fact with respect to these newly asserted bases for Sheffer's claim. Accordingly, the Court OVERRULES NPC's motion for summary judgment on Count III of the Second Amended Complaint, the claim of nonconformance with manufacturers' representations.

5. Count IV: Loss of Consortium

In Count IV of the Second Amended Complaint, Scott Sheffer seeks damages for loss of spousal consortium.[7] NPC argues that because this claim is derivative of Shirley Sheffer's claims, which allegedly lack merit, this claim must be dismissed as well. Because the Court finds that some of Shirley Sheffer's claims survive summary judgment, the loss of consortium claim survives as well. The Court therefore OVERRULES NPC's motion for summary judgment as to Count IV of the Second Amended Complaint.

---

[7] In the Second Amended Complaint, this claim is mislabeled as Count VI.

6. Count V: Punitive and Exemplary Damages (Ohio Revised Code § 2307.80)

In Count V of the Second Amended Complaint, Sheffer alleges that she is entitled to punitive and exemplary damages under Ohio Revised Code § 2307.80, because NPC acted in flagrant disregard of the safety of persons who might be harmed by Aredia® and Zometa®.[8] Notably, this is not a separate cause of action, and NPC did not move for summary judgment on the issue of punitive damages. The Court makes no determination at this time concerning whether punitive and exemplary damages might be warranted.

IV. Conclusion

For the reasons stated above, Defendant's *Daubert* Motion to Exclude Causation Testimony of Plaintiffs' Expert Witnesses (Doc. #32) is SUSTAINED IN PART and OVERRULED IN PART. Dr. Talib Najjar may testify about specific causation, but Sheffer's treating health care professionals may not.

Defendant's Motion for Summary Judgment (Doc. #30) is SUSTAINED IN PART and OVERRULED IN PART. Defendant is entitled to summary judgment on Count I of Plaintiffs' Second Amended Complaint (Design Defect under Ohio Revised Code § 2307.75), but genuine issues of material fact preclude summary judgment on all remaining Counts.

---

[8] In the Second Amended Complaint, this claim is mislabeled as Count VIII.

Date: September 18, 2013

WALTER H. RICE
UNITED STATES DISTRICT JUDGE